Reply to Office Action mailed on September 28, 2010

I. <u>Amendments to the Claims</u>

This listing of claims shall replace all prior versions, and listings, of claims in the application.

Listing of Claims

1-37. (cancelled)

38. (previously presented): A method of effectively treating pain in humans, comprising orally administering to a human patient a therapeutically effective amount of a COX-2 inhibitor together with a dose of an opioid analgesic, wherein the COX-2 inhibitor is nimesulide or a pharmaceutically acceptable salt thereof, and the opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof.

39-46. (Cancelled)

- 47. (previously presented): The method of claim 38, wherein oxycodone and nimesulide are administered in a ratio of 10:1.
- 48. (previously presented): The method of claim 38, wherein the oxycodone is present in the pharmaceutically acceptable salt form.
- 49. (previously presented): The method of claim 38, wherein the COX-2 inhibitor is combined with carrier materials to produce a single dosage form having the COX-2 inhibitor and the opioid analgesic.
- 50. (previously presented): The method of claim 49, wherein one of the carrier materials is a sustained release carrier.

51. (previously presented): The method of claim 38, wherein nimesulide is pro-

51. (previously presented): The method of claim 38, wherein nimesulide is present in an amount from about 0.5 mg to about 1500 mg.

- 52. (previously presented): The method of claim 51, wherein nimesulide is present in an amount of 100 mg.
- 53. (previously presented): The method of any of claims 38, 47 or 49-52, wherein the dose of oxycodone is from 2.5 mg to 800 mg.
- 54. (previously presented): A method of effectively treating pain in humans, comprising orally administering to a human patient an oral dosage form consisting of (i) a COX-2 inhibitor in an immediate release form; (ii) an opioid analgesic in a sustained release form; and (iii) and at least one pharmaceutically acceptable excipient,

wherein the opioid analgesic is oxycodone or a pharmaceutically acceptable salt thereof, and the COX-2 inhibitor is nimesulide or a pharmaceutically acceptable salt thereof.

- 55. (previously presented): The method of claim 54, wherein the dosage form comprises from about 2.5 mg to 800 mg of oxycodone and is administered 2 times per day.
- 56. (previously presented): The method of claim 55, wherein the sustained release form comprises a sustained release carrier selected from the group consisting of an alkylcellulose; a hydroxyalkylcellulose; an acrylic polymer; a fatty acid; a fatty alcohol; a glyceryl ester of fatty acids; a mineral oil or wax; a vegetable oil or wax; a polyalkylene glycol; shellac; zein; and mixtures of any of the foregoing.
- 57. (previously presented): The method of claim 54, wherein said pain is selected from the group consisting of cancer pain, post-surgical pain, low back and neck pain, dysmenorrheal, headache, toothache, pain from sprains and strains, myositis, neuralgia, synovitis, arthritis, degenerative joint diseases, gout, ankylosing spondylitis, bursitis, burns, injuries, influenza or other viral infections, and common cold.

- 58. (previously presented): The method of claim 54, wherein said dosage form comprises particles, wherein said particles have diameter of from about 0.1 mm to about 2.5 mm.
- 59. (previously presented): The method of claim 58, wherein said particles have diameter of from about 0.5 mm to about 2 mm.
- 60. (previously presented): The method of claim 54, wherein the COX-2 inhibitor in an immediate release form is coated onto a tablet comprising the opioid analysesic in the sustained release form.
- 61. (previously presented): The method of claim 56, wherein said sustained release carrier is applied as a sustained release coating; or is incorporated into a matrix along with the opioid analgesic.
- 62. (previously presented): The method of claim 54, wherein said oral dosage form is administered once-daily.
- 63. (previously presented): A method of effectively treating pain in humans, comprising orally administering to a human patient an oral dosage form consisting of a combination of a COX-2 inhibitor and an opioid analgesic in an admixture of excipients, wherein the COX-2 inhibitor is nimesulide or at least one pharmaceutically acceptable salt thereof; the opioid is oxycodone or at least one pharmaceutically acceptable salt thereof, and said pain is pain without inflammation.
- 64. (previously presented): The method of claim 63, wherein the ratio of oxycodone to nimesulide is 10:1.
- 65. (previously presented): The method of claim 63, wherein one of the excipients is a sustained release carrier which provides a sustained release of the opioid analgesic.

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- 66. (previously presented): The method of claim 63, wherein one of the excipients provides a sustained release of the COX-2 inhibitor.
- 67. (previously presented): The method of claim 63, wherein said pain is selected from the group consisting of cancer pain, post-surgical pain, low back and neck pain, dysmenorrheal, headache, toothache, pain from sprains and strains, myositis, neuralgia, synovitis, arthritis, degenerative joint diseases, gout, ankylosing spondylitis, bursitis, burns, injuries, influenza or other viral infections, and common cold.
- 68. (previously presented): The method of claim 38, wherein said pain is cancer pain, post-surgical pain, low back and neck pain, dysmenorrheal, headache, toothache, pain from sprains and strains, myositis, neuralgia, synovitis, arthritis, degenerative joint diseases, gout, ankylosing spondylitis, bursitis, burns, injuries, influenza or other viral infections, and common cold.
- 69. (previously presented): The method of claim 38, wherein the COX-2 inhibitor and the opioid analysis are administered in a single oral dosage form consisting of (i) the COX-2 inhibitor; (ii) the opioid analysis, and (iii) at least one pharmaceutically acceptable excipient.
- 70. (previously presented): The method of claim 38, wherein 4 mg of nimesulide is administered.
- 71. (previously presented): The method of claim 38, wherein said pain is pain without inflammation.
- 72. (previously presented): The method of claim 38, wherein nimesulide and oxycodone are administered once-daily.
- 73. (previously presented): The method of claim 54, wherein said pain is pain without inflammation.

- 74. (previously presented): The method of claim 54, wherein a ratio of oxycodone to nimesulide in the dosage form is 10:1.
- 75. (previously presented): The method of claim 63, wherein 4 mg of nimesulide is administered.
- 76. (previously presented): The method of claim 63, wherein nimesulide and oxycodone are administered once-daily.